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EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

12/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |                                    |  |
|------------------------------|--|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/573,500   | <b>Applicant(s)</b><br>GOLZ ET AL. |  |
|                              | <b>Examiner</b><br>GANAPATHIRAMA RAGHU | <b>Art Unit</b><br>1652            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 43 and 45-73 is/are pending in the application.
- 4a) Of the above claim(s) 48-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43, 45-47, 72 and 73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/27/06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>SEQ ALIGN</u> .                        |

***Detailed Action***

Applicants' election of Group I, claims 43, 45-47, 72 and 73 in the reply filed on 12/07/09 is acknowledged, said response cancelled claims 44, 74 and 75. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 43 and 45-73 are pending in this application, claims 48-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Thus, claims 43, 45-47, 72 and 73 are now under consideration for examination.

***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). This application is a 371 of PCT/EP04/10386 filed on 09/16/2004, which claims the priority of EPO Application No.: 03021637.8 filed on 09/26/2003 and certified copy of said application has been provided.

***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 03/27/06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered and initialed the IDS statement.

***Objections to Abstract***

The Abstract of the disclosure is objected to because, Abstract should be on a separate sheet of paper. Correction is required. See MPEP § 608.01(b).

***Specification- Informalities***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Objections***

Claims 43, 47, 72 and 73 are objected to, due to the following informality: Claims 1-6 recite the abbreviation/term "MGAT-X1" in the claims. Examiner suggests at least in the first recitation of the abbreviation, expanding the term to recite the full form of what the abbreviation stands for. Appropriate correction is required. For examination purposes, examiner interprets abbreviation/term "MGAT-X1" stands for monoacylglycerol acyltransferase.

***Claim Rejections 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 and claims 45-47 depending therefrom and claims 72 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 43, 72 and 73 recite the phrase "...hybridizes under stringent conditions...", but does not recite conditions under which the hybridization must occur. Nucleic acids which hybridize under one set of conditions may not hybridize under other conditions and it is well known in the art that stringent conditions can be described as

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high stringency, medium stringency or low stringency. It is not clear to the examiner as to what type of stringency is encompassed in the above phrase. Thus the scope of the claims is unclear. A perusal of the specification, on page 11, lines 16-27 describes exemplary hybridization conditions, however claims as written do not recite the specific conditions the applicants' intend to encompass. Furthermore, claims 43, 72 and 73 recite the phrase "...complementary strand...", it is not clear to the examiner whether the complementary polynucleotide claimed is full length or partial complement of the claimed sequence. Clarification and correction is required.

***Claim Rejections: 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Enablement***

Claim 46 (directed to a host cell comprising the vector of claim 45 comprising the nucleic acid of claim 43) is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because, while claim 46 is enabling for an isolated host cell transformed with the synthetic nucleic acid as claimed, does not reasonably provide enablement for transgenic multi-cellular organisms or host cells within a multi-cellular organism that have been transformed with the synthetic nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim.

Claim 46 is so broad as to encompass transgenic multi-cellular organisms and host cells transformed with specific nucleic acids, including cells in *vitro* culture as well as within any multi-cellular organism. The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to extremely large number of transformed organisms broadly encompassed by the claims. While methods for transforming cells *in vitro* are well known in the art, methods for successfully transforming cells within complex multi-cellular organisms are not routine and are highly unpredictable. Furthermore, methods for producing a successfully transformed cell within the multi-cellular organism are unlikely to be applicable to transformation of other types of multi-cellular organism as multi-cellular organisms vary widely. However, in this case the disclosure is limited to only host cells *in vitro*. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of host cells within a multi-cellular organism for the production of polypeptide. The scope of claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA)). Without sufficient guidance, expression of genes in a particular host cell and having the desired biological characteristics is unpredictable, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F. 2d 731, 8 USPQ 2<sup>nd</sup> 1400 (Fed. Cir., 1988). It is suggested that the applicants limit the claim to "An isolated recombinant host cell ...".

***Claim Rejections 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 45-47, 72 and 73 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Gimeno et al., (WO 03/053363, in IDS). Claims 43, 45-47, 72 and 73, as interpreted are directed to encompass any nucleic acid molecule that hybridizes under any stringent conditions to nucleic acid molecules comprising the sequence of SEQ ID NO: 1 (also see 112, second paragraph for claim interpretation), vector comprising said polynucleotide, host cells comprising said polynucleotide, method of making encoded polypeptide and a pharmaceutical composition comprising said polynucleotide.

Gimeno et al., (WO 03/053363, in IDS), disclose a polynucleotide and encoding a polypeptide with diacylglycerol acyltransferase activity, said reference polynucleotide having 98% best local similarity to SEQ ID NO: 1 of the instant application and the encoded reference polypeptide having 99.4% best local similarity to SEQ ID NO: 2 of the instant application (see provided sequence alignments), examiner takes the position that said reference polynucleotide would hybridize to SEQ ID NO: 1 of the instant application under recited hybridization conditions. Furthermore, said reference discloses vector comprising said reference polynucleotide, host cell comprising said vector,

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method of making polypeptide and pharmaceutical compositions comprising said polynucleotide (Abstract, entire document; especially pages, 4, 50 and 82-87). Therefore, Gimeno et al., (WO 03/053363, in IDS) anticipate claims 43, 45-47, 72 and 73 as written.

***Allowable Subject Matter/Conclusion***

None of the claims are allowable.

***Final Comments***

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/  
Patent Examiner  
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